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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-11

DATE: **December 16, 2004**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: State Survey Agency (SA) Responsibilities in Enforcing the Gynecologic Cytology Proficiency Testing (PT) Requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

Memorandum Summary

- This memo provides guidance for assessing whether laboratories certified under CLIA for cytology are in compliance with statutory and regulatory requirements for cytology proficiency testing (PT).
- The requirements for proficiency testing are in effect. We strongly encourage all individuals who examine gynecological cytology specimens to enroll and undertake a proficiency test in 2005.
- We have previously not enforced the statutory and regulatory requirements for individual PT due to the absence of a nationwide cytology PT program approved by the Centers for Medicare & Medicaid Services (CMS). Given that a nationwide, CMS-approved PT program now exists, we are establishing dates by which affected laboratories would face enforcement actions if they are not in compliance with the cytology PT requirements.
- While we expect compliance in 2005 based on current law and regulations, we are establishing the following dates by which enforcement actions for laboratories would result if compliance has not been achieved:
  a) June 30, 2005 for laboratories to ensure that all individuals are enrolled in a CMS-approved cytology proficiency testing program;
  b) April 2, 2006 for laboratories to ensure that all individuals have been tested at least once by that program;
  c) December 31, 2006 for laboratories to ensure that affected individuals to achieve a passing score.
- We wish to work with the cytology PT organizations, laboratories, state survey agencies, accrediting organizations, exempt states, and national professional associations to promote fulfillment of the statutory provisions well in advance of the above dates, as our goal is the achievement of full and demonstrated proficiency, rather than enforcement.

Background

The Centers for Medicare & Medicaid Services (CMS), state survey agencies (SAs), and approved accrediting organizations routinely survey laboratories, including those that perform

gynecologic cytology examinations, on a biennial basis. The CLIA statute requires the "periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site PT of such individuals, with such testing to take place, to the extent practicable under normal working conditions." See 42 USC sec. 263a(f)(4)(B)(iv) section 353(f)(4)(B)(iv) of the Public Health Service Act.

These provisions were enacted by Congress to ensure basic protections and accuracy in the gynecological tests upon which millions of women depend for critical information and key decisions regarding their health care.

The CLIA regulations that implement this statutory provision require cytology laboratories and individuals who examine gynecological cytology specimens to enroll in a CMS-approved cytology PT program and achieve a passing score, annually. Specifically:

- 42 CFR 493.801 specifies that, "Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification."

- 42 CFR 493.855 provides that, "To participate successfully in a cytology proficiency testing program for gynecologic examinations . . . ." "(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed [applicable to Maryland]. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score [universally applicable]."

CMS-Approved Proficiency Testing (PT) Programs

Full implementation of cytology PT has taken an extended period of time due to the lack of available and qualified national cytology PT programs, an insufficient number of referenced cytology testing materials, and technical difficulties. However, there are now two CMS-approved cytology PT programs. We expect additional organizations to submit PT program applications in the future.

The State of Maryland Cytology Proficiency Testing Program has been approved to test the proficiency of physicians and cytotechnologists who examine Pap smears. Maryland's cytology PT program currently enrolls only physicians and cytotechnologists who examine Pap smears from Maryland residents. The Midwest Institute for Medical Education (MIME) has also met the statutory and regulatory requirements for CMS approval as a cytology PT program and is accepting enrollments for 2005 from all states. With the approval of at least one national cytology PT program, CMS considers cytology PT to be sufficiently available to permit reasonable enforcement of the CLIA requirements for laboratory enrollment and individual participation in cytology PT on a national basis.

CMS Approach to Ensuring Proficiency Testing

We are mindful of the facts that (a) affected individuals need time to enroll in cytology PT programs and may also wish to participate in additional educational opportunities in advance of

testing, (b) PT organizations and laboratories need time to make logistical arrangements for the testing, and (c) survey agencies need time to incorporate the necessary survey protocols.

In light of these considerations we are providing reasonable time and notice prior to the dates by which the main enforcement provisions will be applied.

In addition, 42 CFR 493.945 provides for up to three re-tests for any individual who fails the first test (for a total of 4 testing opportunities), although the laboratory is required to institute special review procedures after any second PT failure. The April 2, 2006 date specified in this memo refers to the date of the first test. However, each individual must obtain a passing score for their initial year of cytology PT by December 31, 2006.

We fully expect that the enforcement provisions of this memorandum will be unnecessary. We have the highest regard for the professionalism and competency of the nation's cytologists and pathologists. We believe that the readiness of such individuals to demonstrate their ability, the evident public assurance value of having national proficiency testing, and the willingness of the pertinent professional organizations to promote such public assurance will result in individuals being enrolled and tested in 2005. We are providing this memorandum now to promote full communication and the earliest possible compliance with the law currently in effect. We are committed to working with all involved individuals and organizations to achieve that result.

Survey Protocols and Key Survey Dates for Compliance with Cytology Proficiency Testing

In the conduct of surveys beginning January 1, 2005, SAs must accomplish the following:

- ***Awareness***: Confirm that the laboratory director and management staff are aware of the CLIA requirements for cytology PT and of the availability of cytology PT in a CMS-approved cytology PT program. Refer the laboratory to informational sources including the CLIA Web site.
- ***Enrollment***: Confirm by review of enrollment documentation that the individuals examining gynecologic cytology slides are enrolled in a CMS-approved cytology PT program no later than June 30, 2005 during the course of the biennial survey. If, within three months prior to June 30, 2005 the laboratory has not ensured that all individuals are appropriately enrolled, issue an alert notice with content provided by CMS.
- ***Testing Review***: Inquire as to the status of actual testing on the part of individuals who are subject to the testing requirements.
- ***Attestations of Enrollment***: For laboratories that will not be surveyed in 2005, or laboratories that are surveyed prior to June 30, 2005 and prior to their enrollment in a cytology PT program, the SA must receive written attestation and documentation signed by the laboratory director that suffices to confirm that, no later than June 30, 2005, the affected individuals were enrolled in a CMS-approved cytology PT program. Protocols for the attestation and information regarding exempt and accredited laboratories will be forthcoming from CMS.

In the conduct of surveys in CY 2006, SAs must also accomplish the following:

- ***Testing***: Confirm that all individuals examining gynecologic cytology slides have completed at least one cytology proficiency test with a CMS-approved cytology PT

program no later than April 2, 2006. If, within three months prior to April 2, 2006 the laboratory has not ensured that all individuals have been tested, issue an alert notice with content provided by CMS.

- ***System of Re-Testing:*** Confirm that individuals who fail the initial proficiency test are being re-tested in conformance with the procedures of 42 CFR 493.855, if such individuals continue to examine gynecologic cytology slides. Notify the laboratory that each individual being tested must obtain a passing score by December 31, 2006.
- ***System of Controls:*** Confirm that the laboratory has in place procedures for the review of specimens examined by individuals who have failed a second test, and for the appropriate controls with respect to individuals who may fail a third test. We expect these situations to be extremely rare.
- ***Attestations of Compliance***: For laboratories that will not be surveyed in 2006 or are surveyed prior to April 2, 2006, the SA must receive written attestation and documentation signed by the laboratory director that suffices to confirm that, no later than April 2, 2006, all individuals examining gynecologic cytology slides have been tested and that the laboratory is in compliance with all pertinent sections of 42 CFR 493.803, and 493.855. Protocols for the attestation and information regarding exempt and accredited laboratories will be forthcoming from CMS.

With surveys beginning January 1, 2007, SAs must confirm that all affected individuals have both undertaken a test and have achieved a passing score, with the exception of newly-hired individuals. We will not consider a laboratory to be out of compliance with the requirements in the case of newly-hired individuals provided such individuals are enrolled upon their hiring and have completed testing within six months of their initial employment with the laboratory.

The CMS regional office, in conjunction with the SA, will initiate intermediate sanctions or limit the laboratory's CLIA certificate for cytology, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of the CLIA regulations if the laboratory:

- Fails to enroll in a CMS-approved cytology PT program;
- Fails to ensure that all individuals examining gynecologic cytology slides are enrolled in a CMS-approved cytology PT program no later than June 30, 2005, or fails to ensure that such individuals have been tested no later than April 2, 2006;
- Allows individuals after June 30, 2005 to examine gynecologic cytology slides who have not enrolled in an approved cytology PT program, or after April 2, 2006 allows such individuals to examine such slides even though they have not been tested for proficiency; * (See note).
- Fails to ensure that an individual who fails a cytology PT test is retested, if such individual continues to examine slides for the laboratory; or
- Fails to take the required remedial actions specified in the CLIA requirements.

*** NOTE:** CMS will not take enforcement action for failure to complete a cytology proficiency test with respect to any otherwise-qualified individual who is newly hired by a laboratory with less than six months of employment in any laboratory, provided such individual is enrolled in a CMS-approved cytology PT program. This policy is primarily focused on individuals entering the profession from college or a school of cytology.

Additional guidance regarding enforcement actions in cytology PT will be provided to the CMS regional offices.

All questions regarding this correspondence should be directed to the Division of Laboratory Services at (410) 786-3531. We will post contacts for CMS-approved proficiency testing organizations on the CMS website at www.cms.hhs.gov/clia as well as other information regarding cytology PT, Q & As, enrollment and testing procedures and dates. CMS will also notify all laboratories conducting cytology testing about these requirements and will provide these laboratories, professional organizations, and other affected parties a comprehensive rollout package that will be shared with the regional offices and states.

Effective Date: The effective date of this memorandum is January 1, 2005. All surveys conducted on or after this date must incorporate the provisions of this memorandum. Effective January 1, 2005 all surveys must include inquiry as to the status of enrollment and testing in accordance with this memorandum.

Training: The information contained in this announcement should be shared with all CLIA survey and certification staff and managers who have responsibility for the oversight of cytology laboratories. Further details regarding the information cited in this memo with an opportunity to ask questions will be provided to the CMS regional offices and SAs prior to the implementation of the policies stated herein.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management